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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,325	06/04/2001	Stuart A. Fine	AKT-053.02	9479

25181 7590 09/10/2002

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EXAMINER
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CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/10/2002

§

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/787,325

Applicant(s)

FINE ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 97-134 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 97-134 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **CLAIMS 97-134 ARE PRESENTED FOR EXAMINATION**

### **DETAILED ACTION**

#### ***Election/Restrictions***

***This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT***

#### ***Rule 13.1.***

The species are as follows:

- I. A composition and method of use thereof wherein the anti-diabetic agent is a thiazolidinedione and the bioavailable source is vanadium;
- II. A composition and method of use thereof wherein the anti-diabetic agent is a sulfonylurea and the bioavailable source is vanadium;
- III. A composition and method of use thereof wherein the anti-diabetic agent is a benzoic acid derivative and the bioavailable source is vanadium;
- IV. A composition and method of use thereof wherein the the anti-diabetic agent is an alpha-glucosidase inhibitor and the bioavailable source is vanadium;
- V. A composition and method of use thereof wherein the anti-diabetic agent is a thiazolidinedione and bioavailable source is chromium;
- VI. . A composition and method of use thereof wherein the anti-diabetic agent is a sulfonylurea and bioavailable source is chromium;

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VIII. A composition and method of use thereof wherein the anti-diabetic agent is a benzoic acid derivative and the bioavailable source is chromium;

IX. A composition and method of use thereof wherein the anti-diabetic agent is a thiazolidinedione and the bioavailable source is magnesium.

X. . A composition and method of use thereof wherein the anti-diabetic agent is a sulfonylurea and bioavailable source is magnesium;

XI. . A composition and method of use thereof wherein the anti-diabetic agent is a benzoic acid derivative and the bioavailable source is magnesium;

XII. . A composition and method of use thereof wherein the anti-diabetic agent is an alpha-glucosidase inhibitor and the bioavailable source is magnesium;

XIII. . A composition and method of use thereof wherein the anti-diabetic agent is a thiazolidinedione and the bioavailable source is aspirin;

XIV. A composition and method of use thereof wherein the anti-diabetic agent is a sulfonylurea and the bioavailable source is aspirin;

XV. A composition and method of use thereof wherein the anti-diabetic agent is a benzoic acid derivative and the bioavailable source is aspirin;

XVI. A composition and method of use thereof wherein the anti-diabetic agent is an alpha-glucosidase inhibitor and the bioavailable source is aspirin;

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is

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allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Each of the species is related since they claim a synergistic combination and method for the use thereof .

The restriction is deemed proper due to the fact that unrelated combinations of compounds yielding synergistic effects are inherently unpredictable and are hence capable of supporting separate and distinct patents.

It is also noted that one specific synergistic combination of two compounds is known to be chemically distinct from another specific synergistic combination of two compounds and reference to one combination would not necessarily be a reference against the other combination under 35 U.S.C.103.

The following claim(s) are generic: 97, 112, 120, 122, 128 and 134.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

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They have been established as separate and distinct in the pharmaceutical art for the reason stated above. .

Further restriction may be required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

T.J.C.  
August 28, 2002